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Draft Meeting Minutes – June 27, 2013 P&T Committee

Springs Preserve
Banquet Room
333 S. Valley View Blvd
Las Vegas, NV 89107
702-822-7700

Committee Members Present:

Adam Zold, Pharm.D.; Evelyn Chu, Pharm.D.; Weldon Havins, MD; Kevin Desmond, RPh; Michael Hautekeet, RPh; David Fluitt, Pharm.D.; Joseph Adashek, MD

Committee Members Absent:

Shamim Nagy, MD; Constance Kalinowski, MD; Ronald Shockley, MD

Others Present:

DHCFP: Gabriel Lither, Deputy Attorney General; Coleen Lawrence, Chief Program Services; Mary Griffith, RN, Social Services Program Specialist;

Catamaran: Carl Jeffery, Pharm.D.; Kevin Whittington, RPh; Mariellen Rich, RPh

HPES: Beth Slamowitz, Pharm.D.

Others: Tom O'Connor, Novartis; Brad Willie, Novartis; Melissa Walsh, Novartis; Barbara Boner; Ann Childress, MD; Evan Riddle, PhD; Shane Hall, Purdue; Helen Liao, Lilly; Don Iacobellis, Lilly; Zeev Hermausay, Salix; Sandy Sierawski, Pfizer; Michael Dutro, Pfizer; Bret Ferguson, Pfizer; Doug Powell, Forest; Kelly Barfia, Salix; Scott Larson, BMS; Bob Gustafson, Lundbeck; Chris Adams, Lundbeck; Deron Grothe, Teva; Christian Williams, Teva; Karim Michail, Biogen; Lovell Robinson, Abbvie

AGENDA

I. Call to Order and Roll Call

Meeting called to order at 1:00PM
Joseph Adashek, MD, Chairman: We are ready to start, let's start with a roll call from the left, please introduce yourself and what your position is.

Kevin Whittington, RPh: Kevin Whittington, Catamaran

Carl Jeffery, Pharm.D.: Carl Jeffery, Catamaran

Evelyn Chu, Pharm.D.: Evelyn Chu, Pharmacist

Weldon Havins, MD: Weldon Havins, Physician

Kevin Desmond, RPh: Kevin Desmond, Pharmacist

Michael Hautekeet, RPh: Mike Hautekeet, Pharmacist

Joseph Adashek, MD, Chairman: Joey Adachek, Physician and Chairman for today

Gabriel Lither: Gabe Lither with the Attorney General's office

David Fluitt, RPh: Dave Fluitt, Pharmacist

Beth Slamowitz, Pharm.D.: Beth Slamowitz, HP

Coleen Lawrence: Coleen Lawrence, Nevada Medicaid

Mary Griffith, RN: Mary Griffith, Nevada Medicaid

Joseph Adashek, MD, Chairman: First of all, for companies that are here, for public comment, please limit five minutes per individual or organization or agency. In other words, if you are with the same company, you can't have five minutes for five individuals within your company, don't make 25 minutes, please no more than 5 minutes per individual organization or agency. Please limit any comments to new information that the board has not heard. Also, if you see that your drug is preferred, it does not mean that you have to get up here and speak and talk about it. I'm sure there are some exceptions, where a drug was considered preferred and then the board ruled non-preferred, it has not happened since I have been here, but if you did not speak because your drug was preferred, and then became non-preferred, it would be fair to let you speak. So next, we have to approve the previous minutes, but first, is there any public comment now before we get into the drug classes?

II. Public Comment

None

III. Review and Approval of the March 28, 2013 Meeting Minutes

Joseph Adashek, MD, Chairman: I would like to review and approve the meeting minutes from March 28, 2013 meeting. Is there anyone that would like to make a motion?
Michael Hautekeet, RPh: I make a motion to approve the minutes from the last meeting.
Weldon Havins, MD: Second
Joseph Adashek, MD, Chairman: All in favor?
Voting: Unanimous – "Aye"

IV. Status Update by DHCFP

Joseph Adashek, MD, Chairman: Status update from DHCFP.

Coleen Lawrence: Good afternoon. Coleen Lawrence for the record. So I'm going to give you several updates on our State Plan Amendments, which are known as our SPA updates. We talked about this last time, we have a request from CMS to do some clean-up on SPAs for them for the ACA. We had our benzos and barbs SPA for part D that was just approved. There were no qualifications, they just required us to do a SPA update so they can track their changes for the ACA for us. There were no policy changes because third party liability coverage was already in effect for us. So that was approved. We also did a SPA for preventative services which allowed us to get an additional 1% FMAP into our State, which was an additional draw-down for our State. There were no policy changes for us on this either, because we were already covering all the preventive services for adult immunizations for the State and have been for a while now. But we had to put a SPA in so we could bring us the extra 1% FMAP for our State and this is effective January 1. We have been working on a SPA for our end-stage renal disease to change our reimbursement methodology. We will be aligning to what Medicare is doing. This does have an impact to providers and manufactures, there is not an effective date on this yet, we are waiting until CMS approves it. And what we will be doing is changing the reimbursement methodology for how some of the drugs are being billed in the ESRD clinics. So you will want to keep a watch on our website for any of our rate notices on that. If you have any questions, you can call my office and we will let you know. It isn't really a change on coverage, it is more a change on the reimbursement side. We are working on another ACA change which is the closed prescriber network for Medicaid. This was supposed to be implemented a couple years ago, we have not done it. This is also known as OPR, ordering, prescribing and referring practitioners. What that means is that you must be a Medicaid provider to prescribe Medicaid prescriptions. Some states have already moved toward that years ago. Nevada Medicaid has never enforced that, and so we will be moving toward that in a couple phases. We will start with pharmacy because pharmacy systems can be built to enforce that with the NCPDP standard transmission. And then we will move toward the rest of our system, our MMIS system. We want to begin sometime in the summer time, so probably July or August to work with our pharmacy systems. And the last thing, ICD-10 is pretty much here, although it is not going to be implemented until next year. We are already working behind the scenes for ICD-10 in Nevada Medicaid. Pharmacy will be one of the largest systems to be hit with this because we utilize ICD-9 so much right now in our pharmacy world. If you're not familiar with how we use it, we use it a lot in our pharmacy system. We have already cross-walked behind the system our policy for ICD-9 to ICD-10 and survived. So it is going to be a huge education front for us and for our prescribers. We are going to partner with you are out there with our prescribers talking about ICD-10. So every meeting you see me in with a pharmacy, that will be my main soap box on ICD-10. We will absolutely implement the day it goes live. No, we will not accept both codes at the same time. After the go-live date, we will only be accepting ICD-10. The other thing that you may hear and our prescribers will need some help with is education. Nevada Medicaid does not have any funds to help with education for our prescribers. So we are really pushing them to go out and find information on ICD-10. When we met with them last October, we had 500 billers in the room and probably had 15 raise their hand when I asked if they knew what ICD-10 was. The majority were physician based billers. They are really behind the curve on understanding what ICD-10 is right

now. For those of you around the psychiatric community, no, we will not be utilizing DSM-IV or DSM-V, we will be enforcing ICD-10 only. DSM-V is being pushed back according to what we are hearing from the AMA. So that is all my updates.

V. Established Drug Classes

A. Central Nervous System: ADHD/Stimulants

Joseph Adashek, MD, Chairman: Alright, we can move to the established drug classes. The first is central nervous system, ADHD and stimulants. Any public comment?

Don Iacobellis: Hello everyone, my name is Don Iacobellis, and I am an outcomes liaison and clinical pharmacist from Eli Lilly's global outcomes team. I am based out of Lansing, Michigan and happy to be out West in the cool weather here and meet all of you. Thank you very much to providing me the opportunity to make a few brief comments on Strattera in lieu of your review on the ADHD medications today. Please refer to the medical values summary and safety verbatim in the package insert provided to all of you for complete product information. After reviewing the current PDL class for ADHD medications, my understanding for the coverage is a class PA for all the products based upon prescriber specialty and age. I commend the board for all the due diligence in assuring the appropriate use of these products. With that said, our product is the only agent not available for those under 18 years of age based upon a change that was made at last November's meeting. I would request that you consider removing this restriction to make it equal to the other agents within the class. Since none of these have this specific added hurdle for clinicians to access them. As all of you know this unique selective norepinephrine reuptake inhibitor offers proven efficacy in hyperactive, impulsive and inattentive symptoms of ADHD. I would like to highlight briefly three points, in the importance of this products within the Medicaid space. First, it has demonstrated experience in children and adolescence in addition to adults. Efficacy has been established in six trials within these groups including four, six to nine week trials in pediatrics between the ages of six and 18 and one for maintenance between 6 and 15. Strattera is the first ADHD agent indicated for maintenance treatment of ADHD in children and adolescence and can be given as mono-therapy. In clinical trials in children, Strattera was shown to provide continuous symptom relief for up to 24 hours. It has also been supported by various guidelines as discussed within the UMASS class review that is within your packets. And these include the American Academy of Child and Adolescence Psychiatry treatment guidelines which suggest an initial treatment plan inclusive of Strattera, amphetamine or methylphenidate. In addition, the 2011 American Academy of Pediatrics treatment guidelines expanded the age range of children and adolescence that should be evaluated, diagnosed and treated and that is between the ages of four and 18. Amongst the non-stimulant agents, they rank the level of evidence in the treatment of elementary school age children between 6 and 11 highest with Strattera. Second, it's clinical value in patients with ADHD and coexisting disorders. In a double-blind placebo controlled study of pediatric ADHD patients with comorbid anxiety, Strattera significantly reduced the symptoms of ADHD without exacerbating the symptoms of anxiety. In addition, in a study of children and adolescence with comorbid Tourette's Syndrome or chronic motor ticks, our product did not worsen or exacerbate the ticks. Lastly, impact on diversion. It is not a scheduled product. Clinical data in over 2000 children and adolescence with ADHD showed only isolated

incidence of diversion. It also has not shown a pattern of response suggestive of stimulant or euphoria properties due to its different mechanism of action. Strattera can also be used effectively in patients with substance abuse disorders without worsening of symptoms. So in summary, I have highlighted Strattera's demonstrated experience, its clinical value with patients with coexisting disorders and impact on diversion with children and adolescence. I ask that you reconsider, and remove this age restriction so that the providers have this product available to help address unmet medical needs and maximize the opportunity to succeed to successfully manage these patients. I would like to conclude by thanking all of you for your continuous support of these products and commitment to helping serve the patients of Nevada. Thank you.

Joseph Adashek, MD, Chairman: Any other public comment?

Michael Dutro: Hello, I'm Michael Dutro and I'm from the medical division of Pfizer. And I'm here to discuss a new product, Quilivant XR. Quilivant XR is a new extended release liquid formulation of methylphenidate. It is indicated for the treatment of ADHD. It is the only extended release liquid stimulant on the market. Why is it important to have a long-acting methylphenidate available? Well many children are unable or unwilling to swallow a solid dosage form. Parents and schools want to avoid the storage and administration issues as well as the stigma of needing a second dose of a schedule II medication during school, therefore long-acting products are preferred. There are work-arounds for previously not having a liquid long-acting form available, but these have significant limitation as well. So how is Quilivant XR formulated to be a long acting liquid? The methylphenidate is put into solution with polysterex, a polymetric resin very similar to what is used for Kaexelate, in much smaller quantities however. This forms a drug polymer complex via ion exchange. And then these tiny complexes are then coated with various thicknesses of extended release coating. The coated particles are then dried and formulated into a powder for oral suspension. Quilivant XR contains approximately 20% immediate and 80% extended release methylphenidate. So does it work, this liquid long acting form? Well we have done pharmacokinetic studies in both adults and children to show a single dose of Quilivant XR to be 95% bioequivalent to two doses of immediate release methylphenidate. And we have also done a placebo controlled cross-over efficacy study in a classroom setting of children ages six to 12 with ADHD. Results indicated that Quilivant XR provided rapid onset of effect within 45 minutes that was maintained through the entire 12 hour study period. So yes, it does work. So what is the adverse event profile? Well based on the experience we have had with Quilivant in controlled trials the adverse event profile appears to be very similar to other extended release methylphenidate products. There really is no reason to believe it would be any different. Quilivant package insert contains the same adverse event information including the same box warning as other methylphenidate products. We do have package inserts if you would like. So how is it dispensed and administered? Quilivant XR is a powder which is reconstituted with water in the pharmacy similar to antibiotic suspensions to form an oral suspension that is good for 4 months at room temperature. It is dispensed with an oral syringe in one of four different bottle sizes to accommodate common doses. It is dosed once a day in the morning with or without food. The bottle should be shaken for at least 10 seconds before administration. Recommended dose for patients six and above is 20mg once a day and then titrated weekly. So what is the value of this new formulation? Quilivant XR is intended to address unmet need for an extended release stimulant liquid formulation for ADHD, primarily for the pediatric population. What about the

work-arounds that are available now such as capsules that can be opened and sprinkled on apple sauce or dissolved into water. Well there are limited to these as well, not all children can use them. There is taste, texture, palpability issues, causing rejection by children or temporary rejection by children. There can be incomplete dosing because not all the sprinkles consistently reach the apple sauce and not all the apple sauce or the water mixture is consumed by the child. Chewing or crushing the sprinkles can result in compromising the extended release mechanism causing dose dumping of the drug. And then many of the work around products are not less expensive. So really instead of asking why a liquid dosing form be available, it might be better to ask why shouldn't one be available for children? It is the accepted norm for children with medications. When you look at usage of common drugs used in children like antibiotics in ages 6 to 12 years old, 80% of prescriptions are for suspensions. If you look at kids in a more narrow range of 6-7, 95% of prescriptions for amoxicillin are for the suspension. So we think quilivant XR is a very unique formulation of a well-known drug that fulfills a significant unmet medical need especially in school-aged children. We ask that you add it to the PDL so it can be an option for this population. I would be happy to answer any questions if you have any.

Joseph Adashek, MD, Chairman: Thank you. Any other public comment?

Ann Childress, MD: I am Ann Childress. I am a board certified adolescent and child psychiatrist and national ADHD expert and I have the privilege of doing several of the Quilivant Trials. At least at one time I had more patients on the medication than anyone else in the world, so I have a lot of experience and a lot of knowledge about it. I am here today as a private physician because I have worked at Mojave mental health for 14 years, so you know the kind of kids we see. Kids that have a lot of difficulties and often need medication. I can give you my disclosure, obviously I have done research for Nexwave pharmaceutics, which was purchased by Pfizer. I am also consultant advisor and speaker for Pfizer for Quilivant XR and they have also supported me in some other studies. I have a very long list of disclosures that would probably take about 5 minutes, so I won't go through all those, so suffice it to say that I have worked with every ADHD long-acting product that is on the market and actual several that never made it to market. I have done about 100 clinical trials, and about 50 were with ADHD. We did the PK studies, the efficacy and safety studies. I'm not here to say that Quiliviant XR has more efficacy than other drugs, because we have not done head-to-head studies with it. However, it is a long-acting medication, and I think that all the long-acting medications have pretty similar efficacy. The real distinction is the liquid formulation that Dr. Duetro talked about. When kids come to the pediatrician, with an ear infection at 7-8 years old, does the doctor say, "Do you want the big amoxicillin form?" or do they just write out the liquid? They just write out the liquid. With kids with ADHD, we don't have very many alternatives. We have the Daytrana patch, that I worked with. It never really caught on, you slap it on the hip, but there are adhesion issues and skin irritation issues and the kids can pull the patch off at school. We talked about people with trouble with pill swallowing. You can sprinkle a number of medications on apple sauce, although a lot of kids don't like apple sauce. There isn't any really good data with other forms of food like pudding or ice cream, and we want to avoid dose dumping. Some of the pills are really big. I had a mom where I prescribed 30mg of Focalin XR, the next month she came back and slammed that bottle on my desk and said, "Have you seen how big this pill is?" I looked at it and said, "Whoa!" It is big. There are taste issues and the companies have been aware for a long time that there are issues with pills and tablets and Concerta is one there is no work-around with. I only have

one of these, so I can't leave this with you, but McNeil even came up with this beautiful down the shoot, to try teach kids to swallow pills. They talked about tips on swallowing. A lot of people know this is a problem. Kids refuse the medication, and that has been a big issue with my Majove patients. Someone that really needs treatment and the parent comes back and says they can't get the capusule down them, I can't get them down with apple sauce, I find pills in the plants, I find pills in the waste basket, I find pills on the floor, the dog got a hold of a pill. I can't tell how well this medicine is going to work if I can't give the kids an optimal dose. If someone has brain cancer and you are trying to get a pill down them, the parents are going to get it down somehow. With ADHD a lot of times the parents have ADHD too and often times it is just too much of a struggle. I know first-hand, I have a daughter that was 13 before she could swallow pills whole, and thank goodness that she didn't have a chronic condition. But it was very difficult, and as a teenager, we still needed to get liquid antibiotics for her. I get complaints from parents all the time. It is a huge issue in clinical trials, I know because I have had kids throw up on me when we are trying to teach them how to swallow the pills. And in many of the trials we have with kids, they have to demonstrate they can swallow a placebo before we can even enroll in the study. One added issue, I know that DSM-V isn't going to be used right away, however, now the comorbidity with Aspergers and autism spectrum disorders, the exclusion you couldn't diagnose ADHD plus that, but now that has been removed. So now we will be able to ask for more medications for a broader population. Before we were filling out our PAR, if it is Autism, well that isn't ADHD and that is not what the kids are approved for. So that will be another huge issue because these kids have taste and texture and tolerability issues too. So I would respectfully request that Quilivant XR be added to the formulary, I would like to see everything on the formulary, because as a clinician, I know that there are instances where Straterra or Intuniv or Vyvance or whatever is the best medication and so I think it is important to have this as an alternative.

Joseph Adashek, MD, Chairman: Thank you. Any questions? Any other public comment? Ok, drug class review, Catamaran.

Carl Jeffery, Pharm.D.: So here is the current list of how the PDL is now. Why we are here today is the product you just heard about, the Quilivant XR, so that is what brought these products back up for review.

Weldon Havins, MD: Can I ask a question? You had Strattera on a previous slide as current PDL and then non-PDL you have Strattera it says "under 18", there is a black box warning for straterra, is that why?

Carl Jeffery, Pharm.D.: At the third quarter P&T meeting we voted to make it preferred for adults and non-preferred for 18 and under.

Weldon Havins, MD: In spite of the black box warning?

Carl Jeffery, Pharm.D.: Right, yes. So basically a quick overview of the ADHD class. They are the central nervous system stimulants, amphetamines, methylphenidate derivatives. The alpha blockers like clonidine and guanfacine and the other class like Strattera which is a norepinephrine inhibitor. I am not going to go into each of the classes. They have all been shown to be equally effective. There are a handful of head to head trials. The ones I have seen are really small populations or a short duration of

time. It is hard to get the power to show they are significantly better than another. So what our recommendation is to approve these as all clinically and therapeutically equivalent.

Joseph Adashek, MD, Chairman: Alright, any comments from the board?

Weldon Havins, MD: I move we accept them all as all therapeutically equivalent.

Michael Hautekeet, RPh: Second

Voting: Unanimous - "Aye"

Carl Jeffery, Pharm.D.: Our new product we are talking about, I think you heard about it sufficiently, it is a once-daily liquid. It is the approved guidelines from the package insert and the information that is available in the binders, same information as you heard from the speakers. Our recommendation is to add Quilivant XR as PDL and make Strattera as PDL for all ages. Keep the rest the same.

Weldon Havins, MD: I have a question for our pharmacists. How comfortable with adding a drug approved for all ages when there is a black-box warning for under 18?

Carl Jeffery, Pharm.D.: With the Strattera specifically?

Weldon Havins, MD: Yes.

David Fluitt, RPh: Well I think we see a black-box warning with all the drugs, and we have cardiovascular disease with the amphetamine class. I do understand and have respect for that, but I guess when I look at Strattera, I notice there are also some liver toxicities too that has been associated with it, and I have some concerns about that. But the black-box warning is consistent in this class for one reason or another.

Evelyn Chu, Pharm.D.: What was the reason it wasn't approved for under 18 the last time it came up?

Carl Jeffery, Pharm.D.: It was a discussion we had among the board, I don't remember all the details, I wish Dr. Kalinowski was here today because I think she was one that was an advocate to have it available as an alternative for adults.

Joseph Adashek, MD, Chairman: Any other questions or comments?

David Fluitt, RPh: I do see Strattera as having a value in the clinical regimen, I do see that there is a tolerability associated with that medication and if there is any sort of drug liking in the amphetamine class, this drug has some value. Because it does have some warning, I think we need to be prudent with how it is prescribed because I think it does have some real distinct advantages for all ages including those under 18 and I would support it being moved back to PDL

Carl Jeffery, Pharm.D.: And as a caveat, I will just remind the board that we do require prior authorization for every medication in this class for all ages. All kids need a PA regardless if it is preferred or not, and then they need to meet the PDL criteria.

Joseph Adashek, MD, Chairman: Any other questions, comments? Anyone want to make a motion?

David Fluitt, RPh: It just sort of occurred to me because this is a highly abusable class of medications and the structure of the Quilivant has been introduced today. Is there any way to manipulate that, that we are aware of that could cause it to be abused?

Carl Jeffery, Pharm.D.: Nothing that I have seen, but I don't know if the representatives here have anything?

Michael Dutro: Well, we haven't done any studies looking at the likability or anything like that. [Inaudible] When you actually look at it, because the powder form is only available in the pharmacy, the patient is never going to see it in the powder form, they will only ever see it as a suspension. There are probably a lot of consequences with trying to inject it from a size standpoint. It is merely speculation on my part but there is no reason to believe it would be abused more or less. If the powder were available, you could see that as something that someone might try to abuse, but the powder form is only going to be available in the pharmacy. We really have no studies to say it will be abuse more or less than others.

Coleen Lawrence: That is one thing you could work with your Drug Use Review board. You can look at all the drugs in the class and utilization review for trends and analysis. You can ask for a recommendation, because that is what they are there for.

David Fluitt, RPh: I'm talking more about misuse..

Coleen Lawrence: Well that is exactly what they are tasked for is misuse.

David Fluitt, RPh: I've seen Tussionex abused and I could see where this is a suspension and if it were centrifuged, you could have a very potent and dangerous medication on the street. I see the value in the liquid formulation, however, just want to look at the public concern of this product.

Coleen Lawrence: Because we looked at that when Strattera first came out, when it was first introduced on the market, we looked at the overall utilization of the class, and when new drugs are introduced, they review the use and misuse.

Joseph Adashek, MD, Chairman: Are there any other comments or questions? Does anyone want to make a motion now?

Kevin Desmond, RPh: I make a motion that Quilivant XR and Strattera be added to the PDL.

Michael Hautekeet, RPh: Second the motion.

Voting: Unanimous – "Aye"

Joseph Adashek, MD, Chairman: Motion approved.

B. Central Nervous System: Anticonvulsants, Misc.

Joseph Adashek, MD, Chairman: Next is anticonvulsants, miscellaneous. Any public comment? No public comment, Catamaran?

Carl Jeffery, Pharm.D.: We have new a product in this class, Oxtellar XR, oxcarbazapine, extended release tablet, dosed once per day as opposed to twice a day, it falls in the same class with all the others. The anticonvulsants here are all approved for the prevention and treatment of seizure disorders, either as monotherapy or adjunctive therapy. The new product is only approved now for adjunctive therapy, which doesn't make a lot of sense because the Trileptal is approved for monotherapy. Some anticonvulsants are used for migraine, bipolar and fibromyalgia, neuropathic pain and other non-seizure related conditions. With that, every therapy for patients is going to be a little bit different. As a reminder, per the NRS 422 guidelines in your binder, any product on the market on June 30, 2010 needs to be considered preferred, we cannot make any product released before that date as non-preferred. So agents available after that can be made non-preferred. Because this is just an extended release version of a drug that is already available, I'm not going to talk about it too much. Our recommendation is these be considered clinically and therapeutically equivalent.

Joseph Adashek, MD, Chairman: Any questions? Discussion? Do we have a motion?

Adam Zold, Pharm.D.: I make the motion that these products all be considered therapeutically equivalent.

Weldon Havins, MD: Second.

Voting: Unanimous – "Aye"

Joseph Adashek, MD, Chairman: Motion carries.

Carl Jeffery, Pharm.D.: So quick overview of the Oxtellar XR, it is an extended release tablet, indicated for adjunctive therapy only in the treatment of partial seizures, same as the children, down to the ages of 6 years old. There is no direct conversion from the immediate release to the extended release, the dose still needs to be titrated. Something funny too with this product, it has to be administered on an empty stomach, so one hour before or two after meals. I think that can be somewhat of a challenge. Real quick, since the last time we discussed this class, the Potiga we discussed at the last meeting. Since then, there has been a drug warning from the FDA, where it is causing some blue pigmentation in eyes, lips and fingernails. It only seems to be happening over a long period of time, of about 4 years. It isn't known if it is reversible yet. The Potiga does need to be tapered off if the patient does wish to stop the medication. Our proposal is to keep Potiga as non-preferred and to consider the new agent Oxtellar XR as non-preferred and keep the remaining as preferred.

Joseph Adashek, MD, Chairman: Any other questions or discussion?

Michael Hautekeet, RPh: I make a motion to keep the PDL as it is now.

Adam Zold, Pharm.D.: Second

Voting: Unanimous – "Aye"

Joseph Adashek, MD, Chairman: Motion carries

C. Gastrointestinal Agents: Ulcerative Colitis

Joseph Adashek, MD, Chairman: Next GI agents, Ulcerative Colitis. Public comment?

Zeev Hermausay: I am Zeev Hermausay, Pharm.D. with Salix Pharmaceuticals. I would like to talk to the board about Aprisa. Aprisa is a locally acting aminosalicilate indicated for maintenance and remission for ulcerative colitis in patients 18 and older. Aprisa is available in extended and delayed release formulation of 0.375GM capsules. It is given once per day as four capsules without regard to meals in the morning. It is pH dependent, it is the only product with break-up dissociation at a pH of 6, so it is slower than the other agents. With other agents, the solution is pH dependent, Apriso should not be given with antacid products. The mechanism of action is unknown. However it appears to be local and what happens, it blocks the production of arachidonic acid and reduces the inflammation. Approval of Aprisa is based on two randomized, double-blind placebo controlled, multi-centered trials. 562 patients were studied, all were in remission. Their mean age was 46, and roughly equal distribution between men and women. It was assessed by a standard index comprised of 4 scores. At baseline, all were in remission and sub-score of 0-1. In both studies, about 70% of patients remained relapse free, this was found to be superior to placebo. There was also an analysis performed for switch treatment. 79% of those on other treatments remained relapse free at 6 months. This product is category B, not all products in this class are. I will open up to questions?

Kevin Desmond, RPh: So your product only comes in one strength?

Zeev Hermausay: Yes, one strength only.

Kevin Desmond, RPh: How does it differ from Pentasa that is an extended release capsule?

Zeev Hermausay: This one is extended and delayed release, and it is released at pH of 6, as opposed to Pentasa that is released at pH of 6.8. So potentially, it might cover a larger area of GI tract.

Joseph Adashek, MD, Chairman: No other questions? Thank you. Any other questions, comments? Catamaran?

Carl Jeffery, Pharm.D.: A lot of new products in this class now that Asacol is going to be discontinued. Asacol HD will still be available, but the regular will be discontinued. A couple new products on there, we just heard about the Lialda, Desicol. The Desicol is a 400mg delayed release capsule. The Delsicol is made by the same manufacture, but with a different name, same dose, just a capsule instead of a tablet now. Almost all of these are mesalamine, and if you don't know, mesalamine is the active metabolite of sulfasalazine. There are no head-to-head studies, but the studies that are available now show that all the products are equally effective, the new once a day products have been shown to be equally effective as the multi-dose products, with the same amount of side effects. With that information, it is our recommendation these products be considered clinically and therapeutically equivalent.

Joseph Adashek, MD, Chairman: Any questions?

Weldon Havins, MD: I make the motion that these be considered clinically and therapeutically equivalent.

Joseph Adashek, MD, Chairman: I second

Voting: Unanimous – "Aye"

Joseph Adashek, MD, Chairman: Motion carries, Catamaran.

Carl Jeffery, Pharm.D.: We covered the studies a little bit before, but the mesalamine needs to be extended release and enteric coated to get through the acid stomach and into the GI tract. Most of these are indicated for treatment and maintenance of remission. There are a few of the new agents that are only indicated for the maintenance of remission. Depending on where the inflammation is occurring, the suppository or enema may work a little better, but those are not being considered today. The oral therapies are well tolerated. Our proposal is to have the Apriso, Lialda and ASacol HD as non-preferred and make Delzicol preferred keeping Canasa, mesalamine, Pentasa and sulfasalazine as preferred also.

Joseph Adashek, MD, Chairman: Questions, discussion?

Michael Hautekeet, RPh: Motion to keep the PDL as proposed.

Weldon Havins, MD: Second

Voting: Unanimous – "Aye"

Joseph Adashek, MD, Chairman: Motion carries.

D. Multiple Sclerosis Agents

Joseph Adashek, MD, Chairman: Motion carries.

Evan Riddle: I'm Evan Riddle, medical science liaison Biogen Iodec. Biogen strongly advocates for open access to all products, but I will give you a quick overview of our two products, Avonex and Tecfidera. Avonex has been out for 15 years, shares similar efficacy to the other platform injectable products. In particular the annulized relapse rate and the disability progression endpoints. A few areas of differentiation, it is the only self-injection product that is once a week, all the others are more frequent, so it is not surprising it has the best adherence rate of all the injectables. It has the lowest rate of injection site reactions of all the injectables, and among the interferons, it has the lowest rate of neutralizing antibody formation. We are still devoting research into this product and recently introduced a pen/auto-injector that is widely preferred by patients. In addition, we have a titration scheme that has been shown to reduce the flu-like symptoms. Moving to Tecfidera, this product was approved by the FDA in late March of this year. It is an oral medication, dosed twice-daily, indicated for the treatment of relapsing forms of MS. It is a novel mechanism of action. It stimulates the NRF-2 pathway which is a transcription factor that primarily targets the antioxidant response pathway, but it

also has some anti-inflammatory effects as well. It was approved based on two trials. I request Tefidera be added to the preferred list for the treatment of MS.

Joseph Adashek, MD, Chairman: Any questions? Thank you. Anyone else?

Melissa Walsh: I'm Melissa Walsh, I am a scientific director with Novartis. I'm here today on behalf of Gilenya. This is the first once-daily oral disease modifying therapy for MS. It has been out since September of 2010, and has been reviewed by the State before. There were two trials in the initial registration. As of February 28 of this year, over 63,000 patients have been placed on Gilenya world-wide. This equates to over 73,000 patient-years' experience. Of the oral DMT's, Gilenya has the most post-marketing experience and we request that Gilenya be added as preferred on the PDL.

Joseph Adashek, MD, Chairman: Thank you.

Christian Williams: I am Christian Williams Medical Science liaison with Teva pharmaceuticals. I will be providing a brief update with regards to our platform product, Copaxone. In the last year, there have been two new trial sets come out. [sites studies and other information in package insert]. Unlike a lot of the other immunological agents, Copaxone does not require routine monitoring or testing. For anything from liver, thyroid or blood chemistry or neutralizing antibodies and does not have any warnings as related to depression, hepatic injury or any other serious infections. And lastly from the standpoint of a class of drug, it is the only agent for relapsing MS that is a pregnancy category B rating, which is significant given the high percentage of young females in this population.

Joseph Adashek, MD, Chairman: Questions? Thank you. Anyone else? Catamaran.

Carl Jeffery, Pharm.D.: Another complex class with a complex disease state and complex set of medications. These patients are definitely a challenge for the providers to treat. The new products, we should have put them in quotes, because I think the last time we reviewed them was a few years ago, so "New" is a relative term. We have three oral agents and then two new injectable agents for us to review today. As you heard the Avonex, Betaseron, Copaxone and Rebif have been out for a long time and are well established. We try to break them out as easy as we can, we have the injectable agents, interferons we have Avonex, Rebif, Betaseron and Extavia. Then injectable agents, non-interferons, copaxone and Tysabri and then the oral agents, Aubagio, Gilenya and Tecfidera, are the new oral agents we will be talking about. The indications vary a little. Most of the injectable agents have an indication for current treatment in addition to the relapsing forms of MS. The oral agents are really only indicated for the relapsing forms of MS. We have the indications broken out here. I also want to point out, the Tysabri is really indicated for second line therapy. It has some pretty significant side effects that limit its use from first-line treatment. Our recommendation is that within this class, these products be considered clinically and therapeutically equivalent. Because they all show they are effective in the treatment of multiple sclerosis.

Weldon Havins, MD: I move we accept these products as therapeutically equivalent.

David Fluitt, RPh: Second

Joseph Adashek, MD, Chairman: Any discussion or questions? Move to a vote.

Voting: Unanimous – "Aye"

Carl Jeffery, Pharm.D.: So again we will try to break these out a little bit to differentiate the products and give a brief description of the trials that are out. The Avonex, Rebif, Betaseron and Extavia show about a 32-34% reduction in and reduce the development of brain lesion on MRI. These are recommended as first-line by the national guidelines. Most side-effects, flu-like symptoms, including fever, chills, myalgia, and asthenia. Asymptomatic liver dysfunction has been associated with interferons, but liver toxicity is rare. With the other non-interferons, we have the Copaxone and Tysabri. As I mentioned, Tysbri is not first-line, it has to be administered intravenously every four weeks. It is effective, but has PML, and is reserved for patients not responding to other agents. With the Copaxone, it is an established sq injection once a day, been shown to reduce relapse by 29% and reduce lesions as well. When we look at the three oral agents, the Tecfidera is twice a day, the others are once daily. All have been shown to reduce the relapse rate by a pretty good amount. It is hard to compare these to the injectable agents because they are different studies. But they show a 32% reduction in relapse rate for Aubagio and 55% for Gilenya and 44-53% for Tecfidera, also, similar side-effects other than the skin reactions. Our recommendation is to have the MS agent class with Avonex, Betaseron, Copaxone, Extavia, Rebif and Tysabri remain preferred and make Aubagio, Gilenya and Tecfidera non-preferred. With this, we would grand-father all patients who may be on Aubagio, Gilenya and Tecfidera. And then our other thought, and this is up for discussion with the board, is that as it stands now, a patient must try and fail two preferred agents before moving to a non-preferred agent. With this class and the sensitive patient population, maybe we can reduce that to trying one agent in the preferred class before moving to a non-preferred agent.

Joseph Adashek, MD, Chairman: Ok, for discussion, I would agree that we should not make people fail two classes before they can get a non-PDL MS drug. So we can include that in a motion, or I can add it on later. Any other discussion or question.

Evelyn Chu, Pharm.D.: I make a motion to just fail one preferred agent before moving to a non-preferred agent.

Joseph Adashek, MD, Chairman: And include these agents as proposed? Is there a second?

Adam Zold, Pharm.D.: I second.

Joseph Adashek, MD, Chairman: Any other discussion?

David Fluitt, RPh: In doing some research, I found a recommendation for Tecfidera to be considered first line, just because it has a mild adverse profile and it is an oral agent and it seems to have some advantages there. In my mind, it should be considered PDL.

Joseph Adashek, MD, Chairman: Do you have any comments on that? Can you tell me more, do you use that drug?

David Fluitt, RPh: I am seeing a little bit more get switched over because it is an oral agent. When you look at the interferons, you get the flushing associated with it and with the injection concept, we are seeing good results from this. It is a BID dosing. The literature does support, at least what I did on the

med update research, it recommends, “It is reasonable to start newly diagnosed patients with RMS with one of these agents, all the interferons, glatiramer, dimthyl fumarate and teriflunomide.

Joseph Adashek, MD, Chairman: Well is there a…can you comment?

Carl Jeffery, Pharm.D.: Yeah, we have left the oral agents as non-preferred as our recommendation, because in the literature that we have, and I’m glad you brought this up Dave, the information that I have seen, doesn’t say these are always first line, there is really no reason you shouldn’t try an injectable agent first. That is where we are coming from, but I think Dave may have some information that didn’t make it into our reviews.

David Fluitt, RPh: The reason I bring this up is that we don’t want to have people jump through hoops to get these medications. We are having great success and control, reduced MRI lesions and relapse rates, going to an oral dosage form just makes sense to me. I know we’re not supposed to discuss cost, but just take a look at this oral preparation, I would want to do that if that was my diagnosis.

Joseph Adashek, MD, Chairman: Ok, there is a motion on the floor, I think we have to deny it first. We have to amend this motion

Gabriel Lither: What we can do here is offer an amended motion, and Dr. Chu can accept the amendment, but you don’t have to. If you don’t accept the amendment, we can vote on it the way it is. And if you do, we’ll vote on the amended motion. Are you willing to accept the amendment to the motion?

Evelyn Chu, Pharm.D.: I think that is reasonable. I would like to have a choice of an oral agent. I accept the amendment to the motion.

Weldon Havins, MD: I second the amended motion.

Joseph Adashek, MD, Chairman: Ok, further discussion after the amendment

Gabriel Lither: Everyone know what you are voting on now?

Joseph Adashek, MD, Chairman: First line, you fail one, and then you can get a non-preferred. And we are adding Tecfidera as preferred on the PDL

Coleen Lawrence: Mr. Chairman, for clarification, we are going to amend the PDL exception criteria for this drug class.

Joseph Adashek, MD, Chairman: Yes, that’s correct. Any other questions?

Voting: Unanimous – “Aye”

Joseph Adashek, MD, Chairman: Ok a report from Catamaran with new drugs to market and new generics.

VI. Report by Catamaran on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Carl Jeffery, Pharm.D.: In your binder, pretty underwhelming this time around. Nothing that impacts us or the PDL. There isn't anything in there I feel I need to call out. A couple new generics, but none are on our PDL, and some new indications, I'll let you read through those.

VII. Review of Next Meeting Location, Date, and Time

Joseph Adashek, MD, Chairman: Next meeting and location?

Carl Jeffery, Pharm.D.: September 26, 2013, tentatively at this same location.

Joseph Adashek, MD, Chairman: Ok, one more chance for public comment. No, Ok, meeting adjourned.

VIII. Public Comment

None

IX. Adjournment

Meeting adjourned at 2:15 PM